K001638

MAR 4 2002

TITAN IMPLANTS
SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name: O-Ring Prosthetic Attachment
Common / Usual Name: O-Ring Prosthetic Attachment
Proprietary Name:

Establishment Registration Number: Pending

Classification: Attachment Accessory for Class III, Reg. # 872.3640

Performance Standards: N/A

Substantial Equivalence: O-Ring Prosthetic Attachment systems are currently being marketed and distributed by Calcitek. Calcitek currently holds a 510k for O-Ring Prosthetic Attachment (510k # K900545/A), Lifecore Biomedical, currently holds 510k #K970776 for O-Ring Prosthetic Attachment.

Material Composition

Abutment -	Titanium., Ti-6A1-4V
Retaining Part -	303 Stainless Steel
O-Ring -	buna-N Rubber

Testing conducted to assure safety and effectiveness include but is not limited to:

- Dimensional Verification
- Visual Inspection
- Bioburden
- Sterilization Validation

Intended Use:

The device provides of means of attaching a removable prosthetic device to an endosseous implant body. Abutments can be used for overdentures, when hygiene around splinted (clip/bar) case could be a difficulty. The titanium abutment screws directly into the implant for stable overdenture retention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Titan Implants
C/O Lynette L. Howard
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K001638
Trade/Device Name: O-Ring Prosthetic Attachment
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA and DZE
Dated: December 3, 2001
Received: December 4, 2001

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001638

TITAN IMPLANTS

STATEMENT OF INDICATION FOR USE

510(k) Number: **Page 1 of 1**

Device Name: **O-Ring Prosthetic Attachment**

Indications for Use:

The device provides of means of attaching a removable prosthetic device to an endosseous implant body. Abutments can be used for overdentures, when hygiene around splinted (clip/bar) case could be a difficulty. The titanium abutment screws directly into the implant for stable overdenture retention.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001638